

MDIC OVERVIEW

Pamela Goldberg, President & CEO

Jon Hunt, Vice President, Clinical Science & Technology

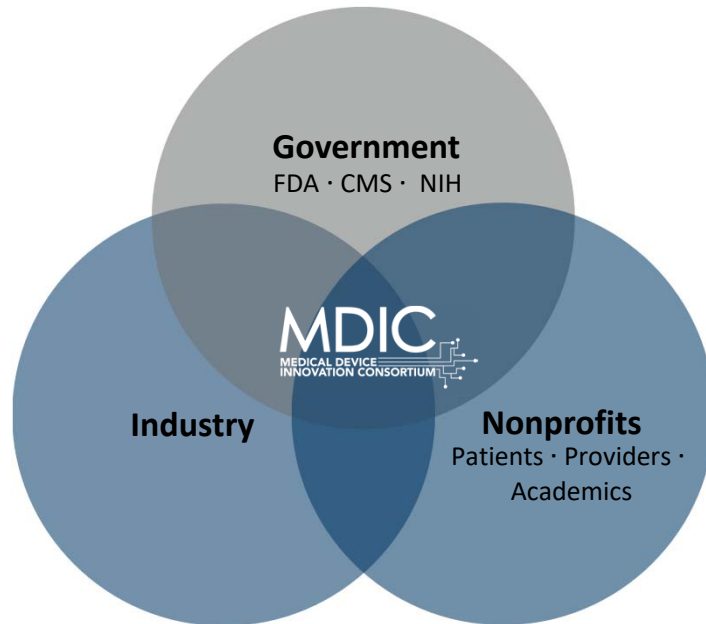
Jithesh Veetil, Program Director, Data Science & Technology

July 18, 2019



What is MDIC?

A 501 (c)(3) and public-private partnership created with the sole objective of advancing regulatory science of medical devices for patient benefit.



Resources · People · Intellectual Capital



HIGHLIGHTS



63 participating member organizations



Leading resource on issues important to the Medtech innovation ecosystem



Initiated nine projects

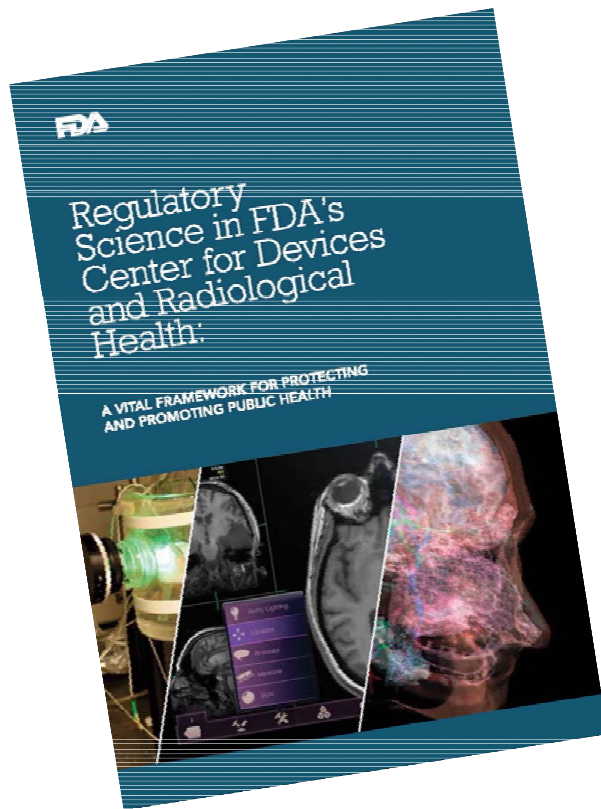


Congressional testimony on modernizing clinical trials



\$35M + funding from grants and contracts for Program initiatives

Defining Regulatory Science



The science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products.

"What we've lacked is a structure like the Medical Device Innovation Consortium that allows for a larger number of parties to come together to develop these projects on an ongoing basis - a significantly more effective way to do research."

- Jeffrey Shuren, MD, JD

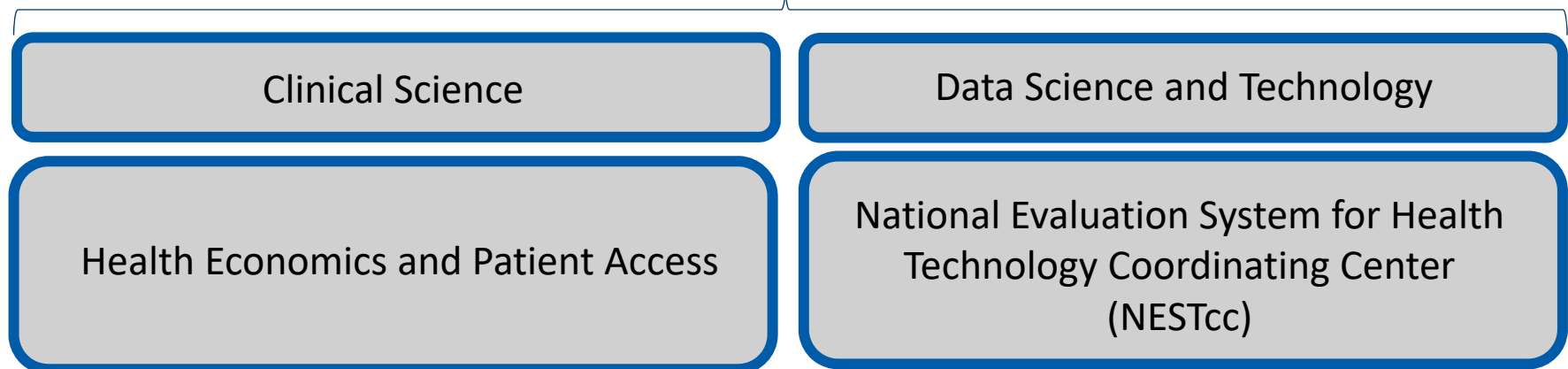
Director of CDRH

MedPage Today, December 4, 2012

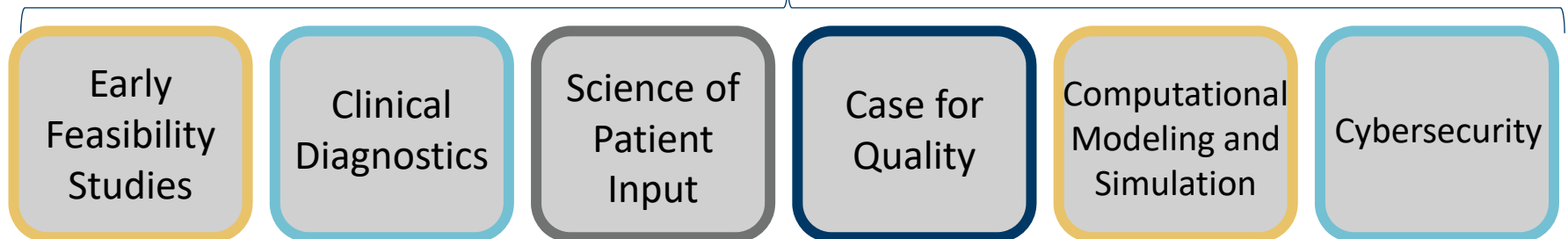
MDIC Initiatives and Program Areas

MDIC supports numerous activities that advance the medical device regulatory process for patient benefit.

MDIC's Core Initiatives



MDIC's Program Areas



Early Feasibility Studies

Advancing regulatory science through innovations in medical device clinical trial efficiency and cost-effectiveness.

FOCUS AREAS

Early Feasibility Studies Site Network Pilot

MDIC

Champion: [Chip Hance](#) | CEO | [Regatta Medical](#)

Program Director: [Liliana Rincon-Gonzalez](#) | MDIC

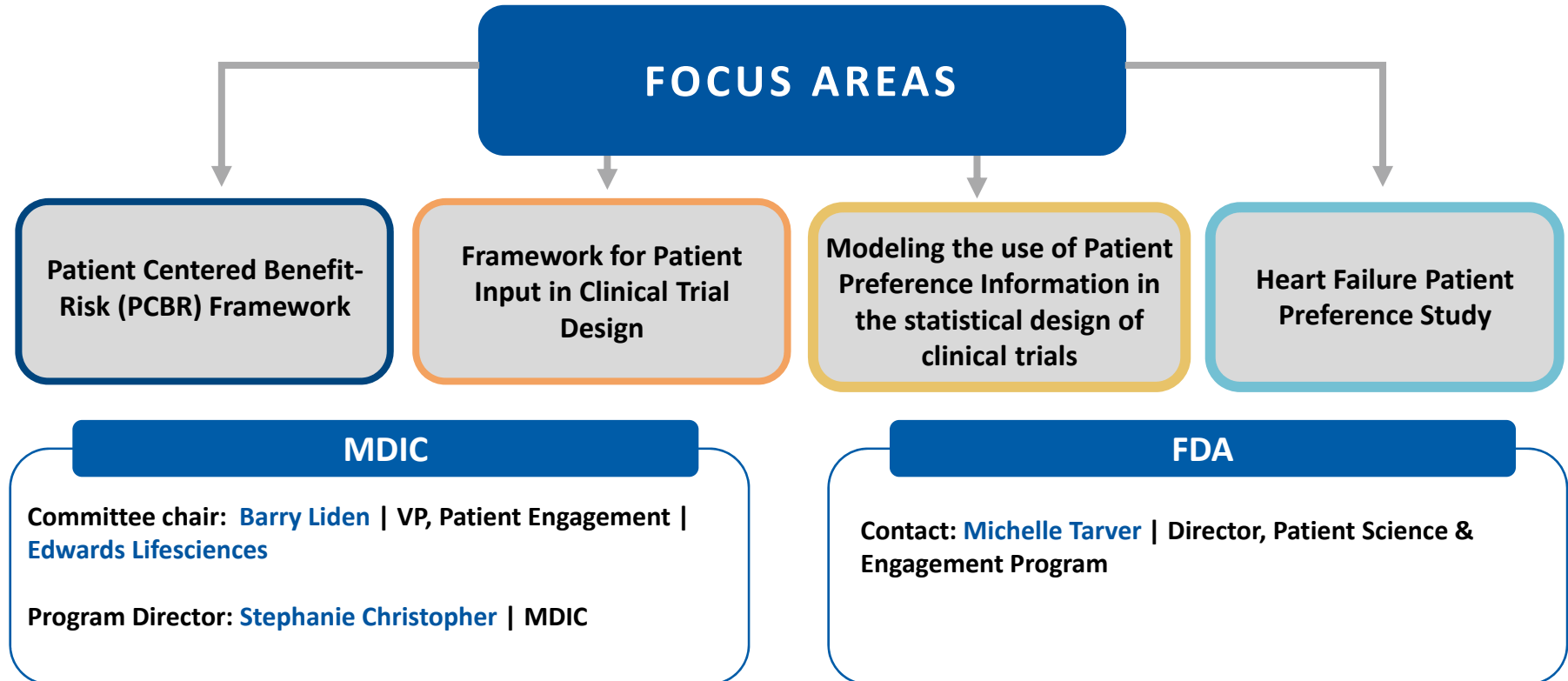
FDA

Contact: [Andrew Farb, MD](#) | Chief Medical Officer | Office of Cardiovascular Devices, CDRH

Contact: [Maureen Dreher, PhD](#) | Acting Assistant Director, Policy and Operations Team | Office of Clinical Evidence & Analysis

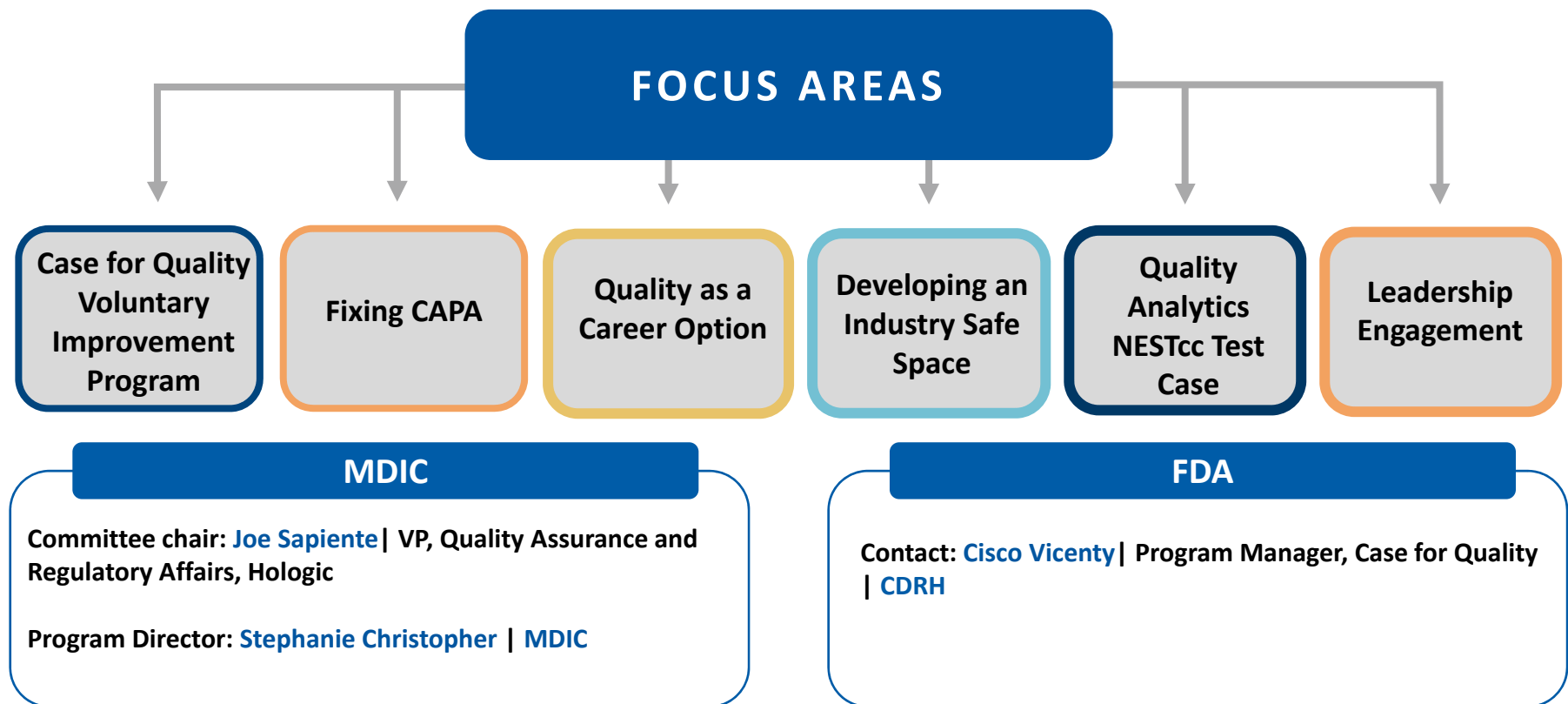
Science of Patient Input

Advancing the science of patient input and improve our ability to include patient perspectives in the development, pre-market approval and post-market evaluation of medical devices.



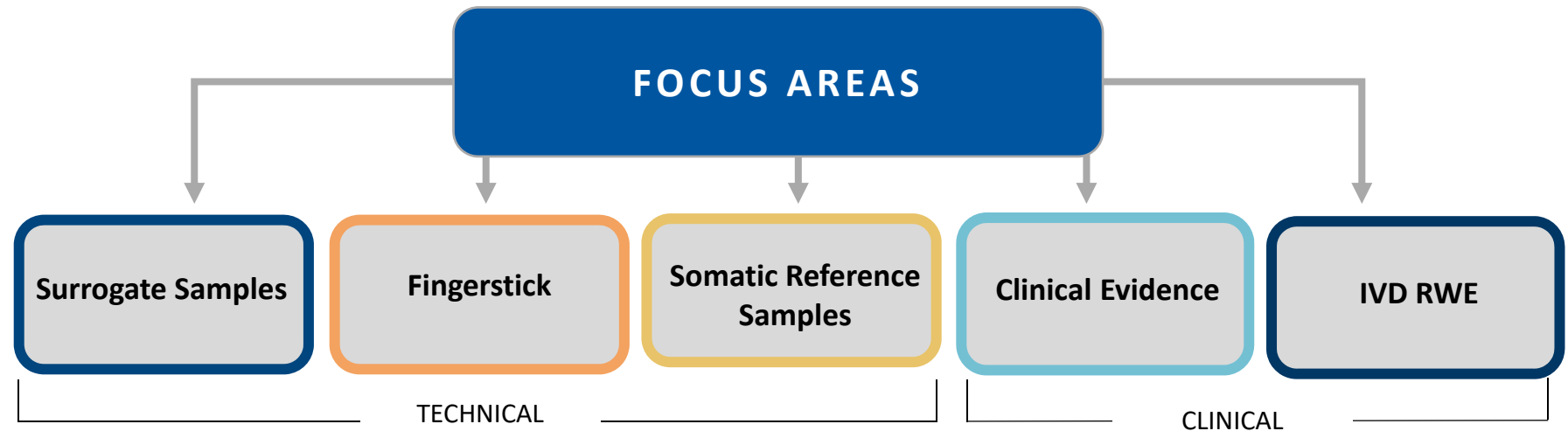
Case for Quality

Elevating the focus of all medical device stakeholders from baseline regulatory compliance to sustained, predictive practices that advance medical device quality and safety to achieve better patient outcomes.



Clinical Diagnostics

Fostering innovation and speed patient access to new IVD tests by developing new tools and methods that will improve processes to assess safety, effectiveness and the value proposition of diagnostic tests.



MDIC

Champion: Tobi Karchmer, MD, MS | SVP, Global Med Affairs and Clinical Development | BD

Program Director: Carolyn Hiller, MBA | MDIC



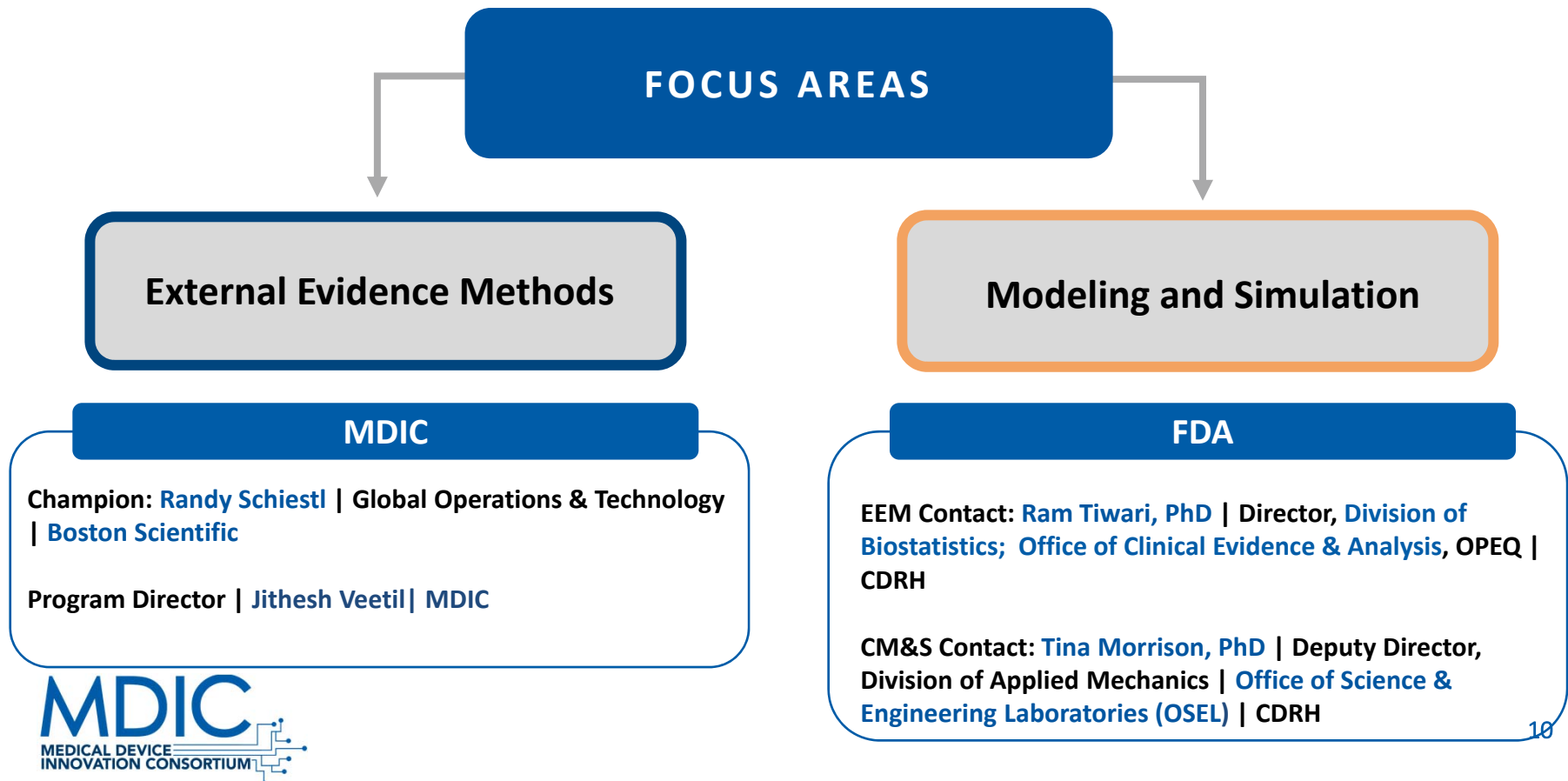
FDA

Contact: Zivana Tezak, PhD | Associate Director for Science and Technology | Office of In Vitro Diagnostics and Radiological Health

Contact: Marina Kondratovich, PhD | Associate Director for Clinical Studies | Office of In Vitro Diagnostics and Radiological Health

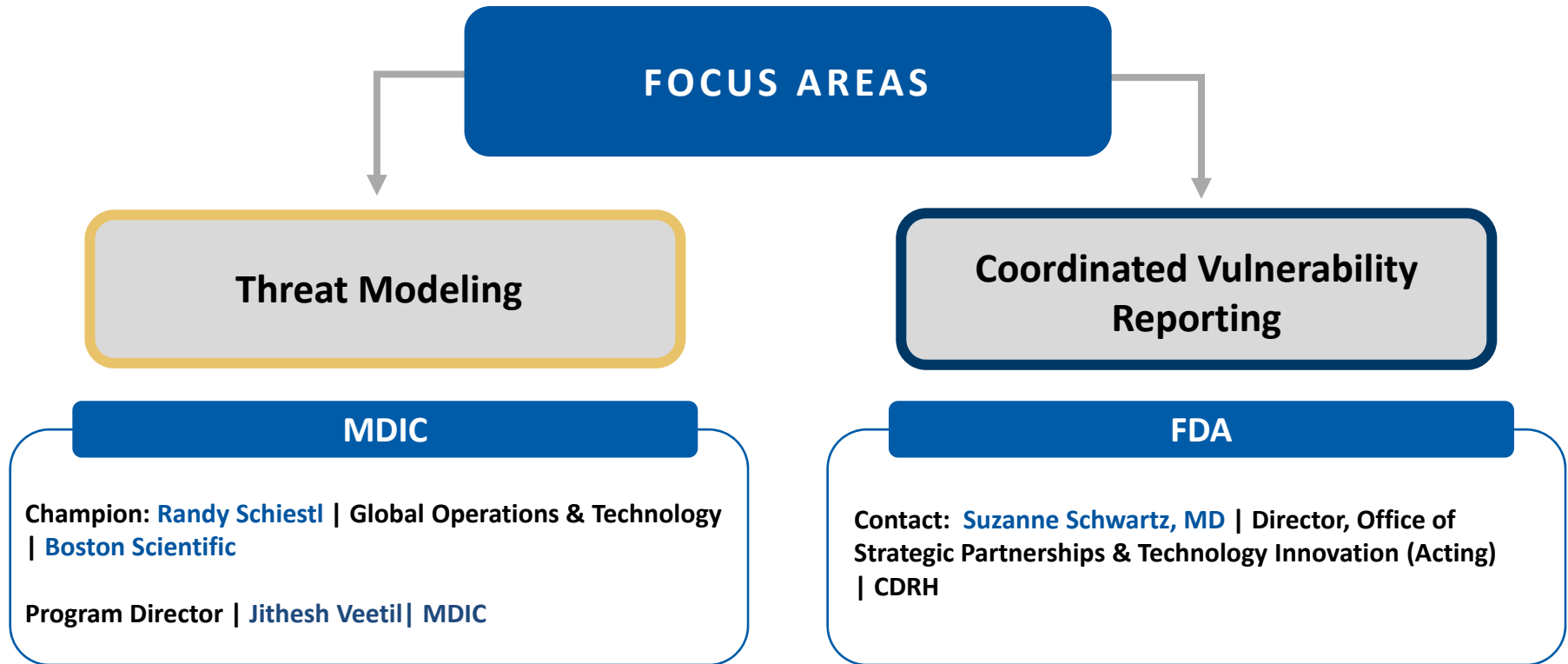
Data Science & Technology

Creating regulatory-grade tools and methods to use advanced data analysis techniques and new technology to accelerate the collection of clinical data, remove barriers to patient access and monitor product safety, quality and effectiveness.



Cybersecurity

Advancing best practices to address cybersecurity threats and vulnerabilities across the medical device ecosystem to maximize product quality and patient safety.



Health Economics and Patient Access

Promoting predictability of evidentiary processes, improving pathways for coverage to speed patient access, and ensuring that patient perspectives are considered.

INITIAL PROJECT INITIATIVE



**HEPA Member Survey and
Survey Report**

MDIC

Champion: [Mike Minogue](#) | President and CEO | [Abiomed](#)

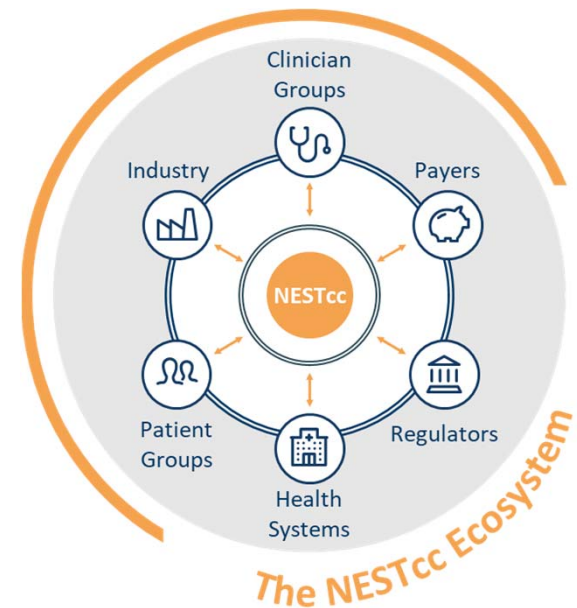
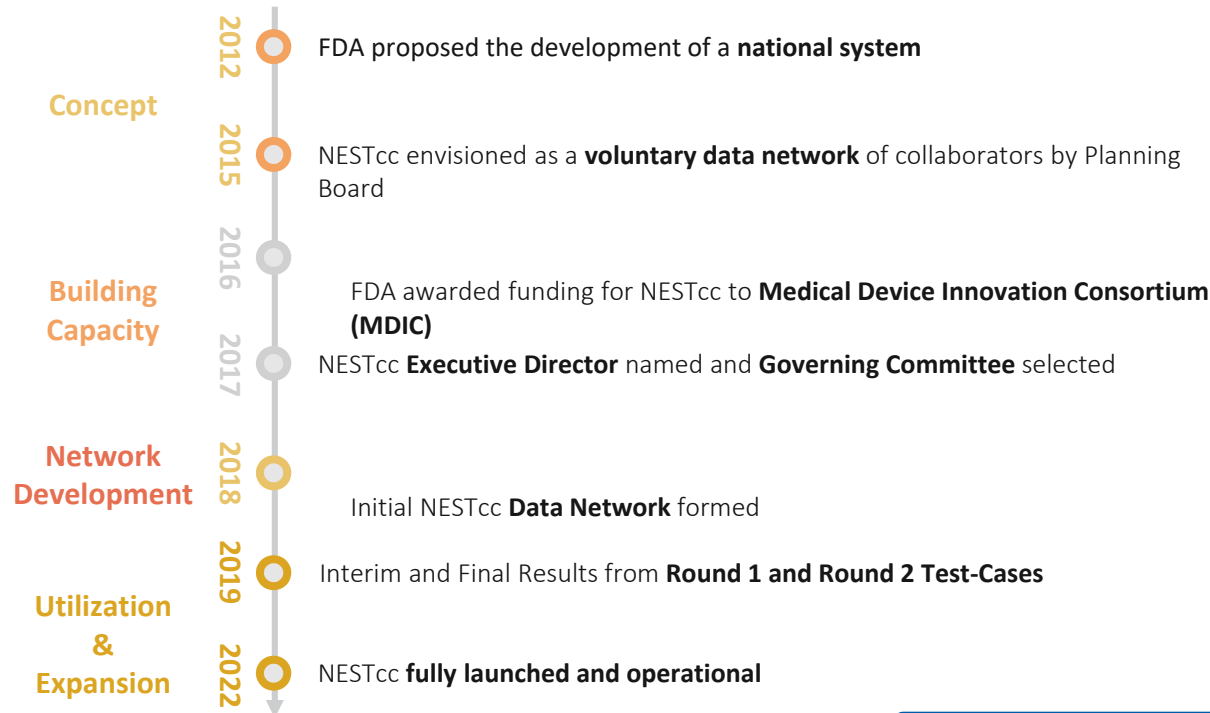
Vice President | [Liz Spurgin](#) | MDIC

FDA

Contact: [Jeff Shuren, MD, JD](#) | Director, Center for Devices and Radiological Health | CDRH

NEST Coordinating Center

NESTcc is an initiative of MDIC that aims to accelerate the development and translation of new and safe health technologies, leveraging Real-World Evidence (RWE), and innovative research



MDIC
 Contact: [Rachael Fleurence, PhD](#) | NESTcc Executive Director, MDIC

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Executive Committee

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Division Vice President and Chief Medical Officer

Kris Kandarpa, MD, PhD | [NIBIB, NIH](#)
Director, Research Sciences and Strategic Directions

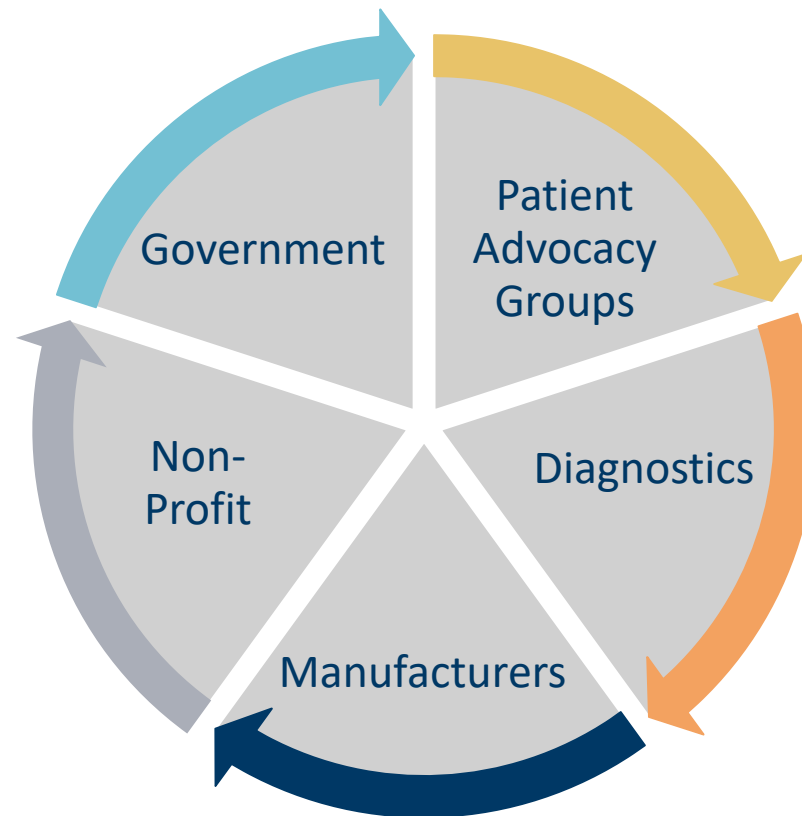
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Joe Selby, MD, MPH | [PCORI](#)
Executive Director

Doug Fridsma, MD, Ph D | [AMIA](#)
President and Chief Executive Officer



MDIC Membership Within the Ecosystem



MDIC members provide guidance and leadership through collaboration to develop solutions for regulatory, scientific, and health economic challenges within the medical device and diagnostic industry.

CURRENT MEMBERSHIP ORGANIZATIONS

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Not pictured: SanterSus, 10x Genomics, Now Diagnostics



Questions?

MDIC

MEDICAL DEVICE
INNOVATION CONSORTIUM

Align. Achieve. Accelerate.



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